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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,585	04/25/2005	Kenshi Kamei	KAMEI2	4282

1444 7590 10/08/2008

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
10/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,585	KAMEI ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10, 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Request filed June 12, 2008 for reconsideration is acknowledged. Claims 10 and 15-19 are pending.

A Declaration filed June 12, 2008 under 37 CFR 1.132 by Dr. Kenichi Ozaki is further acknowledged.

Upon reconsideration, the rejection of record of claims 10 and 19 under 35 U.S.C. 102(a) as being anticipated by Koga et al., Drugs of the Future, set forth in the last Office Action, is withdrawn.

Claims 10 and 15-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Koga et al., Drugs of the Future, in the last Office Action. It was asserted Koga teaches the administration of the compound of instant Formula I, which is designated GM-611, a motilin receptor agonist, to treat idiopathic constipation and constipation-dominant irritable bowel syndrome. On page 271, lines 6-8, Koga states GM-611 is a potential agent in the treatment of constipation.

Applicants argue Koga does not teach GM-611 is administered to treat idiopathic constipation or constipation-dominant irritable bowel syndrome. Applicants urge defecation proceeds from the large intestine, not the small intestine, and apparently conclude such an effect would not accelerate defecation.

In the Ozaki Declaration, as well as Applicants' arguments, reference is made to page 207 of the Koga et al. document. Page 270 appears to be the intended page. Ozaki states "motilin agonists" refer to erythromycin and therapeutic applications thereof, not to GM-611. Further, Ozaki urges distinctions exist between the fasting and digestive states with respect to migrating motor complex activity. Reference is made to

page 207, left column, lines 14-29, wherein both intravenous and oral administrations of GM-611 are given.

No side-by-side comparison between the activity of erythromycin and GM-611, nor administration in the fasting and digestive states, in the treatment of constipation is noted.

Articles directed to the migrating motor complex by R. Bowen and to the gastrointestinal hormone motilin are acknowledged. Cyclic variations in the concentration of motilin are noted.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record of claims 10 and 15-19 under 35 U.S.C. 103(a) as being unpatentable over Koga et al., Drugs of the Future, is maintained.

Koga states **G-611 is expected to have the same clinical applications as erythromycin A** at the bottom of the second column on page 269. See the first full paragraph in column one, page 270, where Koga states previous authors have suggested the presence of motilin receptors exist on colonic smooth muscle, indicating potential therapeutic application of motilin agonists in idiopathic constipation and irritable bowel syndrome. Further, see the Abstract in Sharma et al., "Effect of oral erythromycin on colonic transit in patients with idiopathic constipation: A pilot study," Digestive Disease Dig. (1995), cited on the Information Disclosure Statement filed October 3, 2006. Koga teaches the administration of erythromycin increased stool frequency and decreased colonic transit time when orally administered to patients with

idiopathic constipation. GM-611 exhibits the advantages of being acid-stable when orally administered.

The recitation in the last Office Action beginning with, "In all cases" refers to the requirements of claims 15-18, i.e., constipation, regardless of its etiology, induced by an analgesic; by a functional bowel disorder, such as irritable bowel syndrome; or through age-related decreases in intrinsic colonic reflexes. According to Koga, as suggested by the prior art, the presence of motilin receptors exist on colonic smooth muscle. Thus, one skilled in the gastrointestinal art would have been motivated to administer GM-611 in the treatment of constipation, regardless of its etiology.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 3, 2008

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614